United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-08

Subject: Diagnostic Test Kits for Bovine Spongiform Encephalopathy

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is providing additional information on the product restrictions for veterinary biologics product license and permit applications for diagnostic test kits (including "rapid tests") intended as an aid in the diagnosis of bovine spongiform encephalopathy (BSE).

II. BACKGROUND

Numerous test methods (e.g., immunohistochemistry, ELISA, Western blot) and commercial test kits have been developed to aid in the diagnosis of BSE. Some of these kits have been approved by foreign regulatory officials (e.g., European Union, Japan) for use in their BSE testing programs. Due to recent confirmed cases of BSE in North America and the anticipated increase in surveillance for BSE in the U.S., the CVB will issue U.S. Veterinary Biological Product Licenses or Permits.

In accordance with Title 9 Code of Federal Regulations §102.5(d), U.S. Veterinary Biological Product Licenses will be issued with the following restrictions:

1. Sale and use in the United States restricted to laboratories approved by State and Federal (USDA) animal health officials.

2. Potency testing and distribution and use of BSE test kits shall be under the supervision or control of USDA, APHIS, Veterinary Services under such additional conditions as the Administrator may require.

In accordance with Title 9 Code of Federal Regulations §104.1, U.S. Veterinary Biological Product Permits will be issued with the following restrictions:

1. Sale and use in the United States restricted to laboratories approved by State and Federal (USDA) animal health officials.

2. Potency testing and distribution and use of BSE test kits shall be under the supervision or control of USDA, APHIS, Veterinary Services under such additional conditions as the Administrator may require.

3. Each shipment of biological product distributed and sold under this permit must be accompanied by an original certificate endorsed by a full-time salaried veterinarian of the agency responsible for animal health of the Government of the country of origin, or other assurances acceptable to APHIS, certifying that: 1) All ingredients of animal origin used to produce this product were not obtained from ruminants that have been in any country cited in 9 CFR 94.18 or countries considered to be equivalent status by the National Center for Import Export. 2) During the manufacturing process, the manufacturing facility does not receive, store, or process any ingredients of ruminant origin from countries cited in 9 CFR 94.18. 3) The product complies with all other provisions of 9 CFR 113.53.

III. ACTION

Interested parties should refer to Title 9, Code of Federal Regulations, Subchapter E; Veterinary Services (VS) Memorandum No. 800.50, Basic License Requirements for Applicants; VS Memorandum No. 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale; and VS Memorandum No. 800.73, General Requirements for Immunodiagnostic Test Kits, for guidance in applying for licensure. This information is available on the CVB website:

www.aphis.usda.gov/vs/cvb/regsandguidance.htm

Applications and supporting materials should be submitted to the CVB-Policy, Evaluation, and Licensing for review.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics